

## WHOLESALE AND OTHER DRUG DISTRIBUTOR AND 503b OUTSOURCING FACILITIES **ONLINE** INSTRUCTIONS

**PRINT THIS DOCUMENT AND GATHER DOCUMENTS PRIOR TO STARTING ONLINE RENEWAL – YOU WILL NOT BE ABLE TO PROCEED WITHOUT REQUIRED UPLOADS**

- **You will be required complete the entire renewal application process from start to finish in one sitting**
- The system does not retain any information entered until the application has been completed and submitted
- Have all of your renewal information and copies of documents for upload ready before beginning the online renewal process.
- Fee: **\$250** for all Wholesale and Other Drug Distributors, and **\$200** for 503B Outsourcing Facilities
- Payment Method: online payment by VISA or MasterCard only.

### Required Documents

Information needed for uploads (read to end as some types of distributors have additional requirements)

- Home State license or its equivalent if home state is not South Dakota.
- Most recent Home State, FDA, or VAWD inspection report (conducted within the last 4 years) if home state is not South Dakota. Include any deficiency correction documentation. If inspection is not available, upload a written explanation why.
- FDA inspection report & deficiency correction documents *are required* for 503B and Manufacturing Distributor
- Current Federal DEA certificate, if handling controlled substances.
- *Virtual Manufacturer, provide (a, b, & c); Virtual Distributor, provide (b)*
  - a) For each Contract Manufacturer provide name, address, and copy of agreement first page and signature page **only**.
  - b) 3PL name, address, copy of agreement first page and signature page **only**, and proof of VAWD accreditation for 3PL.
  - c) Copy of Product/NDC list
- Owner or Corporate Officer Certification Form. Form found at <http://doh.sd.gov/boards/pharmacy/wholesalers.aspx>
- If you answered yes to any disciplinary questions, provide an explanation and documentation related to disciplinary action(s).

OTHER Information needed to complete renewal process

- FDA number, if a 503B Outsourcing Facility or Manufacturing Distributor
- Name and address of Registered Agent physically located in South Dakota (<https://sdsos.gov/business-services/corporations/corporate-forms/commercial-registered-agents.aspx>)
- South Dakota Controlled Substance Registration number (if handling controlled substances) (<http://doh.sd.gov/providers/assets/applab.pdf>)